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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,318	02/17/2004	John Ellis	454313-2340.3	1114

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,318	ELLIS ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part) and 3-5, drawn to a composition comprising a nucleotide sequence encoding porcine circovirus type 2 (PCV-2) open reading frame (ORF) 4, classified in class 424, subclass 204.1.

II. Claims 1 (in part) and 2-5, drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and ORF 13, classified in class 424, subclass 204.1.

III. Claims 6 (in part), 7 and 8, drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and an additional pig pathogen, classified in class 424, subclass 199.1.

- Further restriction is required if Group III is elected. Applicant must elect one pig pathogen from the group listed in claim 7.

IV. Claims 6 (in part) and 7, drawn to drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and ORF 13, and an additional pig pathogen, classified in class 424, subclass 199.1.

- Further restriction is required if Group III is elected. Applicant must elect one pig pathogen from the group listed in claim 7.

V. Claims 9 (in part), 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4, classified in class 435, subclass 5.

VI. Claims 9 (in part), 10, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4 and ORF 13, classified in class 435, subclass 5.

VII. Claims 11, 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and an additional pig pathogen, classified in class 435, subclass 5.

- Further restriction is required if Group VII is elected. Applicant must elect one pig pathogen from the group listed in claim 15 and 21.

VIII. Claim 12, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a nucleotide sequence encoding PCV-2 ORF 13, classified in class 435, subclass 5.

- Further restriction is required if Group VIII is elected. Applicant must elect one pig pathogen from the group listed in claim 15 and 21.

IX. Claims 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4 and ORF 13, and an additional pig pathogen, classified in class 435, subclass 5.

- Further restriction is required if Group IX is elected. Applicant must elect one pig pathogen from the group listed in claim 15 and 21.

X. Claim 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition

comprising a nucleotide sequence encoding PCV-2 ORF 13, and an additional pig pathogen, classified in class 435, subclass 5.

- Further restriction is required if Group X is elected. Applicant must elect one pig pathogen from the group listed in claim 15 and 21.

2. The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and II are drawn to distinct compositions related as combination and subcombination. In the same way, Inventions II and IV; V and VI; and VII-X, are all drawn to distinct compositions/methods related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination (ORF 4 and ORF 13) can be practiced without subcombination. In Group VIII, for example, the method of reducing viral load is practiced with a composition comprising a polynucleotide molecule encoding PCV-2 ORF 13. In Group VII, the method uses a composition comprising a polynucleotide molecule encoding PCV-2 ORF 4. The subcombination, SEQ ID NO: 4 has separate utility such as in a method of detecting and quantifying antibodies.

b) Inventions (I and II); (II and IV); (V and VII); (VI and IX); and (VIII and X) are directed to related products/methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not

obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the compositions of Group I and II comprises a polynucleotide construct encoding ORF 4, or ORFs 4 and 13. Groups III and IV, however, re drawn to a composition comprising the elements of Groups I and II, respectively, with an additional pig pathogen. A search for the two types of products is not coextensive. A search of literature pertinent to Groups I or II will not necessarily reveal literature relating to Groups III and IV.

c) Inventions (I-IV) and (V-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be used in a materially different process of using, such as detecting and quantifying antibodies.

d) Restriction between pathogens in claims 7, 15 and 21 is required because each pathogen requires a separate search of the literature. Literature relating to encephalomyocarditis virus is not expected to reveal literature relating to *E. coli*. A search for all of the pathogens would be a serious burden of search.

3. Because these inventions are distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) both in the literature and in the sequence databases, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include (i) an

election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen

Stacy B. Chen
March 2, 2006